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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,613	07/28/2006	Vipulkumar K. Patel	PB60707	8356

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EXAMINER

CHU, YONG LIANG

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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04/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/587,613	Applicant(s) PATEL ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14-23 is/are rejected.
- 7) ☒ Claim(s) 1-9 and 14-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 10-13 have been cancelled by the amendment filed on 02/04/2008.
Claims 19-23 are new by the amendment. Therefore, claims 1-9, and 14-23 are pending in the instant application.

Information Disclosure Statement

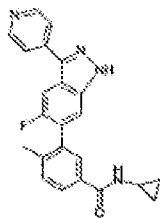
Applicants' Information Disclosure Statement, filed 07/28/2006 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Priority

This application is a 371 of PCT/GB05/00266 filed on 01/27/2005, which claims benefit of foreign priority of U.K. patent application No. 0402138.2 filed 01/30/2004.

Response to Restriction/Election

Applicant's election *without traverse* of Group I (i.e. claims 1-9, and 15-23) and



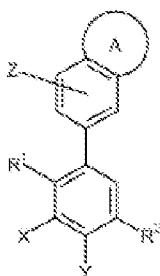
the elected species of the compound as Example 1 of the Specification in the reply filed 02/04/2008 is acknowledged.

Status of the Claims

The withdrawn process claim 14 is rejoined the product claims 1-9, and 14-23.

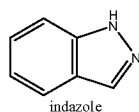
Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of the Formula (I) according to claim 1, wherein:

A is a fused 5-membered heteroaryl ring wherein the 5-membered heteroaryl ring fused



to the phenyl ring is a substituted indazole, wherein **A** is substituted by -

(CH₂)_qaryl or -(CH₂)_qheteroaryl wherein the aryl or heteroaryl is optionally substituted by one or more substituents independently selected from oxo, C₁-6alkyl, halogen, -CN, trifluoromethyl,

-OR⁹, -(CH₂)₄CO₂R¹⁰, -NR⁹R¹⁰, -(CH₂)₄CONR⁹R¹⁰, -NHCOR⁹, -SO₂NR⁹R¹⁰, -NHSO₂R⁹ and -S(O)₂R⁹, and **A** is optionally further substituted by one substituent selected from -OR⁷, halogen, trifluoromethyl, -CN, -CO₂R⁷ and C₁₋₆alkyl optionally substituted by hydroxy;

Z is selected from halogen, C₁₋₆alkyl and -OR²⁷;

R¹ is selected from methyl and chloro;

R² is selected from -NH-CO-R¹¹ and -CO-NH-(CH₂)₄-R¹²;

X and **Y** are each independently selected from hydrogen, methyl and halogen; and the remaining substituents are defined according to claim 1, or a pharmaceutical composition comprising at least one compound thereof.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-9, and 14-23 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds and compositions contain varying functional groups which are chemically recognized to differ in structure, function, and reactivity. The scope of the invention is set in considering the elected species and the preferred embodiments. In addition, a reference, which anticipates one group, would not render obvious the other. Therefore, claims 1-9, and 14-23 will be examined on the merits.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected because it refers to any one of Examples 1 to 6 in the instant specification. A claim should particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention, and should stand alone to define

the invention. Incorporation into claims by express reference to specification in this situation is not permitted, because one must refer back to the specification to determine what applicant is claiming by referring to the examples. It is suggested that applicant insert the name or chemical structures into the claim.

The term "pharmaceutically acceptable derivative thereof" renders claims 1-9, and 14-23 indefinite. By definition, "derivative" is defined as a compound derived or obtained from another and containing essential elements of the parent substance. It is not clear which compound is included or excluded from these claims, because the specification does not define which element of the "pharmaceutically acceptable derivative thereof" of the Formula (I) of claim 1 is essential, and what are the essential elements. The Examiner interprets the term as the compounds of formula (I) according to claim 1. The remaining claims are rejected for depending from the indefinite claims 1, and 7-9.

Claim 19 recites the limitation "the 5-membered ring fused to the phenyl ring is an optionally substituted indazole" in claim 15. The term "optionally substituted indazole" means substituted indazole and non-substituted indazole. There is insufficient antecedent basis for this limitation of non-substituted indazole in the claim, because the indazole ring is substituted by substituents **Z** and $-(CH_2)_q$ heteroaryl according to claim 15.

Claim Objection

Claim 1 is objected to because of the following informalities: **A** is a fused 5-membered heteroaryl ring substituted by $-BR^6$, wherein **B** is defined as a substituent.

However, B is also a symbol of chemical element. It is easy to confuse the substituent **B** to the element B, especially considering that symbol **B** is used as a chemical element in claim 14. Applicant may need to use another letter for the substituent B.

Claims 1-9, and 14-23 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Conclusion

- Claims 1-9, and 14-23 are objected to.
- Claims 1-9, and 14-23 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1626

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626